

# Laboratory Logistics: An Operational Perspective on Precision Medicine

Q&A With *Claudia French*



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**AJMC®:** Would you discuss how you approach your role at Florida Cancer Specialists (FCS) amid the fast-evolving precision medicine landscape in oncology?

**FRENCH:** I am a medical technologist, and my background is in both laboratory medicine and Operational Excellence, [specifically] the study of lean manufacturing and Six Sigma. I am a process person, and in my previous job, I worked for Ortho Clinical Diagnostics and did consulting work in the laboratory space. Three years ago, I came to [FCS] and was hired to oversee both laboratory services and the Operational Excellence program. Basically, my role within [FCS] as it pertains to the lab was to oversee all laboratory services, both in the central lab and the immediate-response labs located in the clinics. There are 2 central labs located in Fort Myers, Florida. One is for FCS, and the other is for AON [American Oncology Network]. We have about 100 small immediate response labs located in clinics in Florida and across the country (AON locations).

About 3 months ago, we completed a move into a new building. We were able to design a new laboratory building. The first floor is 25,000 square feet and houses the FCS central laboratory. The second floor is the AON central laboratory with space for future growth. All the AON and FCS clinics do what we call immediate-response testing. The clinics do CBCs [complete blood cell counts] and limited point-of-care testing for patients seen in the clinic that day. Lab work not performed locally is sent to the central laboratory for testing. This testing includes chemistry and pathology testing.

**AJMC®:** What are some challenges that you have encountered as you work to ensure that FCS is at the forefront of precision medicine?

**FRENCH:** The field of laboratory medicine has evolved dramatically over the years. When I received my training in laboratory medicine, molecular medicine was not part of the training. Now that's the way things are moving—more and more toward molecular medicine, next-generation sequencing. Many laboratory professionals who weren't trained recently don't have experience with molecular medicine. The challenge for me is to hire the right people with the right knowledge.

In the past 3 years, we've added cytogenetics to our test menu to expand our genetics' offerings. We used to do FISH [fluorescence in situ hybridization], and now we do cytogenetics as well. We continue to expand histology and flow cytometry. When we built the new laboratory, we built it knowing that we would probably want to do molecular medicine. We built 2 rooms for pre- and postamplification into the actual plan of the new laboratory so that when we're ready, the build-out will be done and we can move equipment into those rooms and accommodate that testing.

Another current challenge in this field involves weighing the cost of what we do versus what we can get reimbursed [for] until the field settles down and becomes more standardized. For any kind of next-generation sequencing, the mechanical/technical part is not that difficult to set up or to do. The challenge is finding the right partner to supply the informatics needed to interpret those

results. With most of these companies—and I've visited a few—their informatics departments are bigger than their laboratories. That's really where the science is these days. You can find a lot of defects or abnormalities, but understanding what they mean and how they apply is key.

**AJMC®: Could you talk about your approach to navigating the changing reimbursement spectrum and testing landscape?**

**FRENCH:** [FCS] is not an academic institution. We are not in the business of research and development, so we like to buy things that have already been developed and FDA approved. So when we talk about partnering, there are a lot of companies out there that are start-ups, which is in itself the biggest challenge of all. There are so many companies out there right now, and they all do different test panels, and it's very difficult to keep track of all the new technology. Because we're all over the state of Florida and the country, some of the lab salespeople will market directly to doctors in the clinic. There's a process behind every company we deal with, and my background is process improvement. We try within our own group to standardize as much as humanly possible. We have a set of SOPs [standard operating procedures]. We have standard equipment that we buy. We have a standard process, then we can attempt to improve quality. Without a standard, we can't improve, so we start by establishing a standard, and then we try to improve things as we go along. In the molecular world right now, there is no gold standard. That said, we have all these companies that profess to do it better, faster, and for more genes, and it's just hard to make sense of what's real and what isn't real and who is really the best partner because inevitably if we decide to move forward with internalizing this testing, we're going to have to partner with someone.

**AJMC®: Will anything beyond the actual test factor into your decision?**

**FRENCH:** Having the right lab information system that can support next-generation sequencing. Not every lab information system has that capability, and we are in the process of implementing SCC Soft Computer. They have a very robust genetics suite, and there are a few companies that specialize in genetics. Until we have that system up and running with a pathology and genetics suite, we wouldn't even attempt to start doing that testing, because we need that infrastructure to support it.

Regarding reimbursement, again, we are not an institution that exists to develop new testing. What we like to do is to get FDA-approved testing and then implement it in our environment and try to improve quality for our patients. As a centralized lab, we can have a faster turnaround time and have direct communication with the patients' physician and our pathologist. The ability to run in-house would

improve patient care, which truly is our goal. It's all about patient care. In the world of next-generation sequencing, turnaround time is key. We see keeping everything in-house as a great advantage for our patients because it allows us to begin protocols sooner or make decisions that are based on that information sooner instead of having to wait a month.

**AJMC®: Could you discuss the importance of the relationship between oncologists and pathologists at your institution?**

**FRENCH:** When it comes to improving patient care, there is no substitute for good communication. I spent many years doing process improvement within hospitals, where balls are often dropped while doing hand-offs and things seem to fall through the cracks due to a lack of communication. In our particular circumstance as an exclusive-use laboratory, we have a unique situation. We only do testing that is ordered by physicians in our group for their patients. At FCS, we are very dedicated to our patients, and there's nobody more important than those patients. This allows our pathologists to have complete access to that patient's information. The pathologists can partner with our oncologists and have continuous back-and-forth conversations.

I have been in this industry for a lot of years, and I've never been to a place where the communication between the oncologist and the pathologist is so open and free flowing. I think that helps to, first, make a faster diagnosis because there's not a whole lot of wait time. Our pathologists can go ahead and order medically necessary tests, which expedites the turnaround time and the diagnosis and ultimately helps them make treatment decisions faster. And it's kind of an incredible situation that allows them to facilitate patient care in a much faster and more concise way, and all of that is really good for our patients.

**AJMC®: As the field changes, what are some of your goals to ensure that FCS stays at the forefront of precision medicine and oncology?**

**FRENCH:** In addition to hiring the right people, it's about staying current with what's new and sending people to the right seminars and classes. I try to keep up as much as possible by talking with people or reading what I can and doing research. We talk with lots of salespeople, and we gain a lot of knowledge about where things are going in the field. We visit places to understand how others do things. That's basically letting our doctors lead the way. If our doctors believe a particular test would help us treat our patients and provide them with better care, we're going to go ahead and investigate whatever that is and try to bring it in-house, if it makes sense financially. There are a lot of considerations, and obviously the most important consideration is our patients and making sure they get treated when and how they need to be treated to achieve the best possible outcome. ♦